



PT MANDIRI INTI BUANA

K 042239

Jalan Sei Belumai
Desa Dalu 10 A Dusun I
Tanjung Morawa – 20362
SUMUT – INDONESIA

DEC 16 2004

Tel +62-61-7944880
Fax +62-61-7944882

510 (K) SUMMARY

1.0 Submitter:

Name : PT MANDIRI INTI BUANA
Address : Jl. Sei Belumai, Desa Dalu 10 A Dusun I
Tanjung Morawa – 20362
SUMUT – INDONESIA
Phone No. : +62-61-7944880
Fax No. : +62-61-7944882

Date of Summary Prepared:

2.0 Contact Person:

Name : Mr. Sasitharan Nair
Phone : +62-61-7944880
Fax No. : +62-61-7944882

3.0 Name or the device:

Trade Name : 1) Flexiskin and
2) Multiple or Customers' Trade Name
Device Name : Powder Free Nitrile Blue Examination Gloves,
Blue, Non Sterile
Common Name : Examination Gloves
Classification Name : Nitrile Blue Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device:

Class I Nitrile Examination Gloves, 80LZA, powder free, that meets all the requirements of ASTM standard D 6319-00a^{E3} and FDA 1000 ml Water Leak Test.

5.0 Description of The Device

The Powder Free Nitrile Examination Gloves, Blue, Non Sterile meets all the requirements of ASTM standard D 6319-00a^{E3} and FDA 1000 ml Water Leak Test.

6.0 Intended Use of The Device

The Powder Free Nitrile Examination Gloves, Blue, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's to prevent contamination between patient and examiner.



7.0 Summary of The Technological Characteristics of The Device

The Powder Free Latex Examination Gloves, Blue, Non Sterile (Contains 50 micrograms or less of Total Water Extractable Protein per gram) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimension	D 6319-00a ^{E3}	Meets
Physical Properties	D 6319-00a ^{E3}	Meets
Freedom from Pinholes	D 6319-00a ^{E3} FDA 21 CFR 800.20	Meets
Powder Residue	D 6319-00a ^{E3} D6124 - 01	< 2 mg/glove
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (No primary skin irritation)
	Dermal Sensitization	Passes (No contact sensitizer)

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510 (k) process.

10.0 Conclusion

It can be concluded that The Powder Free Nitrile Blue Examination Gloves, Blue, Non Sterile will perform according to the gloves performance standards referenced in Section (7) above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed device.



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1.0 Premarket Notification 510 (k) Submission Applicant:

Name : PT MANDIRI INTI BUANA
Address : Jl. Sei Belumai, Desa Dalu 10 A Dusun I
Tanjung Morawa – 20362
SUMUT – INDONESIA
Country : INDONESIA
Phone No. : +62-61-7944880
Fax No. : +62-61-7944882

1.1 Activity of Applicant:

Manufacturer Repacker Importer
 Consultant Contact Manufacturing Other

1.2 Contact Person:

Name : Mr. Sasitharan Nair
Phone : +62-61-7944880
Fax No. : +62-61-7944882

2.0 Truthful and Accurate Statement: As shown in Attachment A

3.0 Indication for Use Statement: As shown in Attachment B

4.0 Trade Name:

Proprietary or Trade Name: 1) Glovetex and
2) Multiple Free Nitrile Examination Gloves, Blue,
Non Sterile.

5.0 Name and Location of ACTUAL Manufacturer:

Name : PT MANDIRI INTI BUANA
Address : Jl. Sei Belumai, Desa Dalu 10 A Dusun I
Tanjung Morawa – 20362
SUMUT – INDONESIA
Country : INDONESIA
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6.0 Labels, Labeling and Advertisings:

Copy of dispenser box labeling is provided in Attachment C

7.0 Classification Information:

7.1 Device Class: I

7.2 Substantial Equivalent Device Description: Nitrile Examination Gloves

7.3 Product Code

<input type="checkbox"/> Vinyl – 80 LYZ	<input type="checkbox"/> Latex – 80 LYY
<input type="checkbox"/> Polymer – 80 LZA	<input type="checkbox"/> Latex (Powdered) – LYY
<input type="checkbox"/> Specialty – 80 LZC	<input type="checkbox"/> Latex (Powder-free) – 80 LYY
<input type="checkbox"/> Finger Cot – 80 LZB	<input type="checkbox"/> Latex (hypoallergenic) – 80 LYY
<input type="checkbox"/> Other – 80 FMC	<input type="checkbox"/> Latex (powder-free/hypoallergenic- 80LYY
<input checked="" type="checkbox"/> Nitrile – 80 LZA	<input type="checkbox"/> Latex (protein label claim) – 80 LYY

8.0 Specifications:

Size	230	WIDTH, mm
XS	230	70 ±10
S	230	80 ±10
M	230	95 ±10
L	230	111 ± 10
XL	230	115 ± 10

SINGLE WALL THICKNESS, mm (minimum)	
Finger	0.08
Palm	0.08

	BEFORE AGING	AFTER AGING At @ 100°C for 22 hr
Tensile Strength	14 MPa, min	14 MPa, min
Ultimate Elongation	500 % min	400 % min

ASTM Pinhole Requirements: Single, General Inspection Level G-1, AQL 2.5

8.1 Reference Performance Standards:

ASTM D 6319 – 00a^{E3} Adherence: [V] FULL [] PATRIAL



9.0 Quality Assurance Testing (of Finished Gloves):

Does quality assurance conform to ALL ASTM D 6319-00a^{E3} procedures and FDA water leak test?

[V] YES [] NO

A summary of Quality Assurance Testing Procedure, Sampling Plan and Acceptance Criteria for Gloves Inspection and Testing, and Device Test Report of Compliance of finished gloves are provided in Attachment D, E and F

10.0 Dusting Powder

Information of Powder used is provided in Attachment

11.0 Finished Powder Free Gloves:

Information for Finished Powder Free Gloves is provided in Attachment G

12.0 Colour Additive:

A material safety data sheet for the colour additive used and colour fastness test report are provided in Attachment I and J

13.0 Glove Biocompatibility:

Powder Free Nitrile Examination Glove, Blue, Non Sterile has been sent for biocompatibility test i.e. FDA Primary Skin Irritation Test and FDA Dermal Sensitization Test were performed on the finished gloves and the test result are provided in Attachment K and L respectively.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

DEC 16 2004

Mr. P. Sasitharan Nair
Quality Regulatory Manager
PT Mandiri Inti Buana
Jalan Sei Belumai, Desa Dalu 10 A Dusun 1
Tanjung Morawa-20362
SUMUT-INDONESIA

Re: K042239

Trade/Device Name: Powder Free Nitril Examination Gloves, Blue, Non Sterile
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: November 23, 2004
Received: November 26, 2004

Dear Mr. Nair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042239

Device Name: POWDER FREE NITRILE EXAMINATION GLOVES, BLUE NON
STERILE

Indications For Use: powder Free Nitrile Examination Gloves. Non Sterile
is a disposable device and made of Synthetic
Polymer that exhibits rubber like Characteristics
Intended For Medical Purpose that is worn on the
examiner's hand or finger to prevent contamination
between patient and examiner.

Prescription Use CFR 801.109 AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzette M. Chinn DMD
(Division Sign-Off)
Division of Anesthesiology
Infection Control, Dental Devices
510(k) Number K042239

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TOTAL P.01